IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

JAN K. VODA, M.D.	§	
	§	
Plaintiff,	§	
	§	
vs.	§	Case No. 5:09-cv-00095-L
	§	
MEDTRONIC, INC. and	§	
MEDTRONIC VASCULAR, INC.,	§	
	§	
Defendants.	§	

MEDTRONIC'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW OR IN THE ALTERNATIVE FOR NEW TRIAL WITH RESPECT TO INFRINGEMENT AND DAMAGES

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Defendants Medtronic, Inc. and Medtronic Vascular, Inc. hereby move the Court for judgment as a matter of law ("JMOL") or in the alternative for a new trial on infringement and damages under Rule 50(b) of the Federal Rules of Civil Procedure.[1]

I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

The Court held a jury trial beginning on January 17, 2012. Before the case went to the jury, Medtronic moved for JMOL under Rule 50(a) for insufficient evidence of infringement and damages.[2] The Court denied the motion and Medtronic proceeded with its case-in-chief. The jury returned a verdict for Plaintiff on direct infringement, inducement of infringement, contributory infringement, and willful infringement and awarded damages of $9.9M on January 26, 2012. The Court entered judgment on January 27, 2012.[3]

II. LAW AND PROCEDURE FOR RULE 50(b) MOTION FOR JMOL AND ALTERNATIVE MOTION FOR NEW TRIAL UNDER RULE 59

Under Rule 50, JMOL should be granted "if a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue."[4] On a motion for new trial, the trial court has the power to set aside a jury verdict that is "against the weight of the evidence." *McHargue v. Stokes Div. of Pennwalt Corp.*, 912 F.2d 394, 396 (10th Cir. 1990). The standard for granting a new

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[1] Exhibits referenced are included in the Appendix Medtronic's post-trial motions.

[2] *See* Trial Transcript, at 1016:25 – 1029:16. All Trial Transcript cites may be found in Exhibit 1.

[3] *See* Judgment (Dkt. No. 273).

[4] Fed. R. Civ. P. 50(a)(1); defendants also request relief under FRCP 60, to the extent that any relief requested is not covered by Rules 50 or 59.

trial is lower than that for granting JMOL, in that it does not require the evidence to be viewed in the light most favorable to the non-moving party. *Henning v. Union Pac. R.R. Co.*, 530 F.3d 1206, 1216-17 (10th Cir. 2008) ("A motion for a new trial, however, neither requires nor even envisions that the court view the evidence in such a light."). In addition, where the trial court believes that the judgment for damages is excessive, that is, against the weight of the evidence, it may order a remittitur and alternatively direct that there be a new trial if the plaintiff refuses to accept it. *See, e.g.*, *Henning*, F.3d at 1216-17; *Wicklund v. Pac. Cycle, LLC*, 2010 U.S. Dist. LEXIS 86602 (N. D. Okla. Aug. 23, 2010). Plaintiff failed to meet his burden of proof of direct infringement, inducement of infringement, contributory infringement, willful infringement, and damages, and as a result there was no legally sufficient evidentiary basis for a reasonable jury to find for Dr. Voda on those issues. In addition, the verdict was against the weight of the evidence.[5]

III. ARGUMENT

A. Plaintiff Failed to Carry His Burden of Proving Direct Infringement, and the Great Weight of the Evidence Is to the Contrary.

This case only involved method claims. To prove infringement of the asserted method claims, "a person must have practiced all steps of the claimed method." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009). "A method claim is not directly infringed by the sale of an apparatus even though it is capable of performing only the patented method .... A method claim is directly infringed only by one practicing

[5] In addition to the arguments presented herein, Medtronic submits that the evidentiary rulings and jury instructions discussed in Medtronic's Motion for New Trial, filed contemporaneously with this Motion, substantially and adversely affected Medtronic's rights and accordingly warrant a new trial.

the patented method." *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-75 (Fed. Cir. 1993); *see Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1335 (Fed. Cir. 2008). Accordingly, in this context Dr. Voda "must either point to specific instances of direct infringement or show the accused device necessarily infringes the patent in suit." *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007). Dr. Voda proved neither.

1. There is no evidence in the record of any specific instances of direct infringement.

Dr. Voda does not claim that Medtronic performs every step of the claimed method.[6] Instead, Dr. Voda argued that Medtronic induces physicians to perform the steps of the method. It is not enough for Dr. Voda to show the EBU is capable of infringement—Dr. Voda must show specific instances of direct infringement.

But Dr. Voda failed to show any specific instance of direct infringement by a physician in the record, even though Medtronic sold more than 1.5 million EBU catheters between 2003 and 2011. Dr. Voda was obligated to produce evidence of physicians who actually used the EBU to touch the opposite wall of the aorta for 1.5 cm or more, such as fluoroscopy images of the procedures, but he did not. We know this type of fluoroscopic evidence is available because Dr. Voda was able to produce these images in the previous *Voda v. Cordis* case, but he did not—or could not—do so here, even though the EBU is still in use.[7] Dr. Voda did not name a single doctor who used the EBU and could actually

[6] Trial Transcript, at 575:10-15.

[7] *See* Plaintiff's Trial Exhibit 107.

confirm that it contacted the aortic wall for 1.5 cm; he also admitted that he had no evidence in the form of fluoroscopy images of EBU catheters used in live patients.[8]

Dr. Voda's infringement expert, Dr. Chronos, also failed to provide any evidence of an EBU actually being used to contact the aortic wall for more than 1.5 centimeters in a live patient, despite the fact that fluoroscopy images are commonly taken during every angioplasty and are available and stored in hospitals with patient records.[9] Dr. Chronos conceded that he did not try to find images of actual patients to support the conclusions in his report, instead claiming that obtaining evidence of the length of contact from a live patient is impossible:

> Q. So my question was, did you make an effort to go out and try to find actual pictures of actual patients to support the conclusions in your report?
>
> A. Maybe you're not understanding me. So let me just clarify so you fully understand what I'm saying. I'm in the cath lab every week. People are using EBUs and Vodas and everything every week. I'm seeing angiograms in our cath conferences every week. Am I going specifically to pick an angiogram from a PAC system to do what with? **Because you can't on an angiogram in a live patient measure anything.** You have shown us endless pictures of angiograms in patients. So did I turn up in Oklahoma City with an angiogram specifically to do what with? No.[10]

We know that this is factually incorrect—Dr. Voda provided fluoroscopy images from actual patients in the *Cordis* case and used them to show the length of contact of XB catheters.[11]

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[8] *See* Trial Transcript, at 560:11-25.

[9] *See* Trial Transcript, at 738:4-13.

[10] Trial Transcript, at 739:8-20 (emphasis added).

[11] Trial Transcript, at 665:12-15.

Neither Dr. Voda nor Dr. Chronos provided any evidence establishing that a single instance of direct infringement had occurred. Dr. Voda claimed that he used some version of the EBU 10-12 times in the 1990s, but admitted that he could not recall the details of the procedures, had no images from the procedures, and that he had taken no direct measurements with respect to the length of contact on the opposite wall of the aorta.[12] Similarly, Dr. Chronos claimed that he had used EBU catheters a number of times many years ago, but could not recall the details, did not measure the length of contact, and does not have any images from of any of those procedures.[13] But none of this matters because neither Dr. Voda's nor Dr. Chronos' use of an EBU catheter is legally sufficient to establish infringement. Dr. Voda's use of an EBU catheter cannot be an infringing use, and use by Plaintiff's experts Dr. Voda and Dr. Chronos is insufficient to establish infringement. *See ACCO Brands, Inc. v. ABA Locks Mfr. Co*., 501 F.3d 1307, 1313 (Fed. Cir. 2007) (finding "no evidence of direct infringement" where expert expressed no opinion on "whether users other than himself used the [accused device] in the infringing mode").[14]

Further, the cadaver demonstration offered by Dr. Voda does not show direct infringement either. Dr. Chronos and Dr. Uretsky testified that the conditions inside the aorta of a cadaver heart are markedly different than the conditions in the aorta of a live

[12] Trial Transcript, at 544:13-18, 545:10-24, 546:13-23.

[13] Trial Transcript, at 734:1-18, 736:6-9, 737:1 – 738:3.

[14] In addition, Dr. Voda and Dr. Chronos claimed to have used the EBU many years before the relevant period (2003-2011).

patient.[15] Dr. Chronos could not determine the length of contact shown in the cine image that he included in his report.[16] The only testimony regarding the length of contact shown in the cine image from the cadaver was Dr. Uretsky's testimony that the length of contact was less than 1.5 cm.[17]

The only measurements taken by Dr. Chronos were after the cadaver heart was taken out of the water bath, placed on a table on top of a towel, dried off, and the top of the aorta removed.[18] While Dr. Chronos did not have a picture of the moment when the measurement was made, the provided picture shows a finger touching the back of the aortic wall.[19] Dr. Chronos could not confirm whether the finger that was putting pressure on the side of the aorta affected the length of contact.[20] Even if Dr. Chronos' measurement had been accurate—and there is no evidence it was accurate—a single measurement from a cadaver heart and conducted in the furtherance of litigation cannot prove that every single one of the 1.5 million procedures using hundreds of different EBUs, performed by thousands of different doctors, actually touched the wall for more than 1.5 cm.[21]

Dr. Voda has failed to provide legally sufficient evidence for a reasonable jury to find direct infringement. Dr. Voda has failed to show, circumstantially or otherwise, that

[15] Trial Transcript, at 764:5 – 765:5, 1129:3 – 1130:18.

[16] Trial Transcript, 765:4-6.

[17] Trial Transcript, at 1135:2-24.

[18] *See* Trial Transcript, at 765:11-14.

[19] Trial Transcript, 766:17 – 767:3.

[20] Trial Transcript, at 766:17 – 767:3, 1136:16-1137:9.

[21] Trial Transcript, at 1142:18-1143:24; *see also*, Medtronic's Motion for New Trial, Section III. A.

any doctor has actually performed all of the steps of the claimed method with any of the hundreds of different versions of the EBU sold between 2003 and 2011. In fact, the available evidence conclusively proves that in many instances EBU catheters were used in a way that does not infringe. It was therefore incumbent on Dr. Voda to prove that any EBU catheters he accused were actually used in an infringing manner, and he offered absolutely no evidence to that effect.

2. The EBU does not necessarily infringe because the undisputed evidence establishes that EBU is used in non-infringing radial procedures.

Absent evidence of specific instances of infringement, Dr. Voda must show that all EBU catheters necessarily infringe. *ACCO Brands*, 501 F.3d at 1313. But the evidence is uncontroverted that the EBU catheter is used for the brachial, radial, and axillary procedures, and that none of these uses infringe. Dr. Voda admitted that (a) the EBU is used for the radial approach and (b) using the EBU to perform the radial approach does not infringe:

> Q. So if a physician uses an EBU through the radial approach, that does not infringe your patent?
> A. It does not.[22]

Dr. Voda testified similarly at other points in the trial that the radial approach is a non-infringing use,[23] and that the EBU "certainly can be used for" the radial approach.[24] Mr. Horrigan testified not only that the EBU can be used for a radial approach, but also

[22] *See* Trial Transcript, at 613:10-12.

[23] *See* Trial Transcript, at 613:10-12, 613:24-614:13, 615:1-7.

[24] *See* Trial Transcript, at 526:15-19.

that he has personally observed doctors use the EBU for radial procedures.[25] Similarly, Dr. Uretsky testified that he has personally used the EBU catheter to perform radial approach angioplasty.[26] In addition, Mr. Schmiel of Boston Scientific testified (and his testimony is supported by a scientific survey) that in the United States, the EBU is one of the most popular catheters for the radial approach.[27] It is undisputed that the EBU does not necessarily infringe.

3. The EBU does not necessarily infringe because Dr. Voda admits that not all femoral approach uses of the EBU infringe.

In addition, there is uncontroverted evidence that the EBU does not necessarily infringe even when used in the femoral approach. Dr. Voda testified that if the EBU was used via a femoral approach as depicted in certain Medtronic brochures it would not infringe.

> Q. I want to turn back to Exhibit 69 for a moment, Defendants' Exhibit 69, and look at the illustration just for one other point. We established that you don't believe these are reliable predictions of what will actually happen inside the body, right?
> A. That is correct.
> Q. I want to ask if someone actually inserted an EBU catheter like the catheter shown in item one, that would not infringe, correct?
> A. (No response.)
> Q. Item one, is the one that dips down --
> A. Yes.
> Q. -- below?
> A. Yes, it would not. That's correct.[28]

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[25] *See* Trial Transcript, at 1064:16-1065:6.

[26] *See* Trial Transcript, at 1128:22-24.

[27] *See* Trial Transcript, at 1095:12-13 (playing of video recording of deposition of Daniel Schmiel, at 132:11-21 (Dec. 21, 2011) (Exhibit 2).

[28] Trial Transcript, at 622:11-6:23:19.

Even Dr. Voda's infringement expert admitted that the EBU does not necessarily infringe. When asked whether he could testify that every use of an EBU catheter would result in 1.5 cm of contact with the opposite aortic wall, Dr. Chronos said "I'm not willing to say yes or no," and instead said only that Medtronic could not "say definitively that it *doesn't* happen in a million patients."[29] Of course, it was Plaintiff's burden to prove infringement, not Medtronic's burden to disprove it.

All of this testimony is undisputed and demonstrates that no reasonable fact finder could have concluded that use of the EBU *necessarily* infringes or that Plaintiff proved specific instances of direct infringement. The weight of the evidence is contrary to the verdict.

B. Plaintiff Failed to Prove Active Inducement of Infringement.

In addition to proving the underlying direct infringement, to prove indirect infringement by inducement, Dr. Voda must establish that Medtronic (1) encouraged or instructed physicians how to perform the method described in claims 1 or 2 of the '213 patent; (2) possessed the specific intent to encourage this infringement, and not merely that Medtronic had knowledge of the physician's acts alleged to constitute infringement; (3) knew of claims 1 or 2 of the '213 patent; and (4) knew that the acts it was encouraging constituted actual infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011). "Knowledge" in this context means actual knowledge or willful blindness; mere recklessness or negligence is insufficient. *Id.*, at 2070. Dr. Voda failed to prove that Medtronic encouraged or instructed any doctor, had the requisite

[29] Trial Transcript, at 727:14 – 728:9 (emphasis added).

intent to do so, or that Medtronic knew that any of its actions would induce actual infringement. Dr. Voda failed to show a single doctor received any instructions on how to use an EBU catheter in an infringing manner, or that any doctor followed any instructions from Medtronic.

1. The Instructions for Use do not instruct any doctor to engage the aortic wall for any length, let alone 1.5 cm.

The only instructional material that is included with a catheter is the Instructions for Use (IFU). Dr. Voda admitted that the IFU is generic and does not mention the opposite aortic wall or any length of contact.[30] The IFU is not unique to the EBU. Medtronic distributes the same IFU with every one of the hundreds of other catheters it sells, including catheters that Dr. Voda confirmed did not infringe (such as Medtronic's Champ and MAC catheters).[31] The IFU does not teach doctors how to specifically use the EBU to engage the opposite aortic wall for 1.5 cm or greater and cannot be the basis of Dr. Voda's inducement claim.

2. Dr. Voda adduced no evidence that any Medtronic employee instructed any doctor to engage the aortic wall for any length, let alone 1.5 cm.

Dr. Voda claimed that both he and his expert Dr. Chronos had used the EBU, and they are the only doctors identified in this case alleged to have used the EBU in the claimed manner. As explained above, they legally cannot be the direct infringers. But in addition, to prove Medtronic liable, Dr. Voda was required to show that they were induced to infringe, and the undisputed evidence establishes that they were not. Neither

[30] Trial Transcript, 566:10-22.

[31] Trial Transcript, 625:12-15, 627:8-10.

Dr. Voda nor Dr. Chronos received any written or verbal instructions from Medtronic regarding the EBU. Dr. Voda failed to identify even a single instance of any Medtronic employee instructing any doctor to engage the aortic wall for 1.5 cm with an EBU. Dr. Voda specifically admitted he had never received any brochures for the EBU prior to the lawsuit.[32] In fact, Dr. Voda could not recall ever receiving any instructions of any kind from a Medtronic employee related to the EBU catheter.[33] He never used an EBU catheter after this lawsuit, so it was impossible for Dr. Voda to have been induced to infringe the method. Dr. Chronos similarly testified that he never received any instructions of any kind from anyone at Medtronic and had never even had a general discussion with anyone from Medtronic related to the EBU.[34]

Similarly, there is no evidence that any other doctor received any Medtronic EBU instructions to use the EBU in an infringing manner, or that any doctor followed any such instructions.[35] Dr. Uretsky confirmed he had never received any instructions or ever seen an EBU brochure before this case.[36] Dr. Voda admitted he is not aware of a single instance of any doctor receiving instructions on how to use the EBU:

> Q. Sure. You're not aware—and when I say you don't remember, we're not worrying about things you don't remember, you don't remember any other doctor who said he received or she received instructions from Medtronic about how to use the EBU and then went and followed those instructions?
> A. So when you say any other doctor, other than who?

[32] Trial Transcript, at 548:19-25.

[33] Trial Transcript, at 556:16 – 557:5.

[34] Trial Transcript, at 738:1-3; 741:12 – 742:2; 742:13-16.

[35] Trial Transcript, 1125:2-9.

[36] Trial Transcript, 1122:14-20, 1125:2-5.

Q. Other than you.
A. Other than me. I don't recall. No.[37]

Jason Acebo confirmed that Medtronic does not teach doctors how to use the EBU. Mr. Acebo testified that in his seven years of selling EBU catheters, he has not used brochures with doctors, in particular because if he provided the doctors "with a slick marketing piece saying we're better than everyone else, they are going to laugh in my face."[38] Mr. Acebo confirmed that doctors have never requested any Medtronic marketing brochures from him.[39] Mr. Acebo further testified he never provided any verbal instructions on how to use a Medtronic guide catheter.[40] Both Dr. Voda and Dr. Chronos confirmed that they learned how to use guiding catheters during medical training and never look to salespeople for instructions on how to perform angioplasty procedures.[41] Dr. Uretsky specifically testified he has never relied on any Medtronic marketing materials to perform an angioplasty procedure, and never uses Medtronic marketing materials in training doctors how to perform angioplasty procedures.[42]

Mr. Acebo's testimony, and the testimony of the physicians, are consistent and make sense because guide catheters are a relatively inexpensive commodity product[43]

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[37] Trial Transcript, at 561:12-19.

[38] Trial Transcript, at 986:5-13.

[39] Trial Transcript, at 986:14-16. Dr. Chronos speculated that "this type of literature is given to physicians" in general, but he did not identify a single doctor, including himself, who actually received the accused Medtronic brochures. *Id.*, at 693:3-6.

[40] Trial Transcript, at 973:19 – 974:16.

[41] Trial Transcript, at 513:13 – 514:5, 678:4 – 679:13, 754:22 – 755:2, 973:19-25.

[42] Trial Transcript, at 1122:21 – 1123:6, 1124:14 – 1125:1.

[43] Trial Transcript, at 963:4-13.

compared to other cardiovascular interventional products. Sales representatives spend time with physicians selling more important and expensive items, like stents, that cost thousands of dollars.[44] These more expensive products drive revenues for medical device companies and full-source contracts with hospitals. Medtronic's training programs further show the importance of stents over catheters. Mr. Acebo testified that out of two weeks of initial training, only a couple of hours were spent on guide catheters.[45] Medtronic's limited training on guide catheters focuses on the different catheter lines and shapes, not any engagement by catheters along the opposite aortic wall.[46] In fact, even in the limited time spent on catheters, Mr. Acebo testified he promoted the kink resistance and torqueability—which relates to the construction of the catheters in general—not any particular shapes or any engagement along the opposite wall.[47]

Mr. Acebo further testified that he does not provide brochures or verbal instructions to physicians regarding the location or distance of contact of the EBU because physicians are not concerned about the length of contact on the opposite wall of the aorta. Instead, the physician is looking for the tip to make sure that the tip is engaged and not damaging the coronary artery.[48] Dr. Voda admitted he does not pay attention to the contact along the opposite aortic wall during a procedure with the EBU because he focuses on "other aspects, how the catheter seats, how easy it manipulates what happens

[44] Trial Transcript, at 967:2-11.

[45] Trial Transcript, at 979:12-21.

[46] Trial Transcript, at 979:22 – 980:24.

[47] Trial Transcript, at 968:16 – 970:10.

[48] Trial Transcript, at 970:14-19.

when I advance the catheter in the left main, is it coaxial"—Dr. Voda "was not interested to see the straight segment or curved segment on the opposing aortic wall."[49] Dr. Uretsky agreed with Mr. Acebo and Dr. Voda that the length of contact is not important to the doctor.[50]

Dr. Voda did not adduce any evidence that Medtronic ever provided written or verbal instructions to any doctor, much less any evidence that any doctor used any Medtronic instructions to perform an angioplasty in an infringing manner.

3. Dr. Voda failed to identify even a single marketing piece that instructs doctors to engage the aortic wall for 1.5 cm with an EBU.

Beyond the fact that there is no evidence that Medtronic actually provided any written or verbal instructions to any alleged direct infringer, the marketing materials themselves do not instruct physicians to infringe. Dr. Voda failed to identify even a single marketing piece that instructs doctors to engage the aortic wall for 1.5 cm with an EBU. None of Medtronic's marketing documents teach a doctor to engage the aortic wall for any length of contact, let alone 1.5 cm, because the EBU is not designed to do so.

Dr. Voda admitted as much—he merely provided his conclusory opinion that the figures from the brochures "teach" him how to engage for 1.5 cm because none of the materials mention 1.5 cm or any length of contact.[51] Dr. Chronos' testimony was similarly conclusory: that Medtronic's brochures "teach" him how to engage the aortic wall for 1.5 cm, even though the brochures do not disclose 1.5 cm of contact in the text or

[49] Trial Transcript, at 547:18 – 548:13.

[50] Trial Transcript, at 1158:2-7.

[51] *See* Trial Transcript, at 518:11-19, 627:19 – 628:16, 630:20 – 631:5.

figures.[52] Mere conclusory statements are insufficient to support a finding of inducement. *See Team 7, LLC v. Protective Sols., Inc.*, 759 F. Supp. 2d 698, 705 (E.D.N.C 2010). Indeed, Dr. Voda contradicted his own conclusory statements by testifying that figures in brochures are wholly unreliable.

> Q. So it is true that we should not rely on brochures as evidence of what actually happens when you use a catheter in a live patient?
> A. That is correct.[53]
>
> * * *
>
> Q. So, to the extent that you have drawn any conclusions from these brochures in your direct testimony, or otherwise, we should not rely on those?
> A. No, we should not rely.[54]

Because Dr. Voda believed the brochures are wholly unreliable, he cannot also claim that he relied on them to teach 1.5 cm of contact.

Even if one could rely on the brochures, Dr. Voda admitted that Medtronic's brochures—such as Plaintiff's Exhibits 6, 7, 78, 183, and Defendants' Exhibit 69—do not show 1.5 cm of contact.[55] Dr. Voda specifically stated "as long as you keep showing me the promotional material, it will be my opinion that it will be the same"; one cannot tell from looking at the brochures if they depict 1.5 cm of engagement.[56] Dr. Voda has admitted that the very brochures that he is relying on as "teaching" doctors to practice the methods in the '213 patent actually show less than 1.5 cm of engagement, or show an

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[52] *See* Trial Transcript, at 698:17 – 699:12, 700:12-17, 701:4-9.

[53] Trial Transcript, at 621 :8-11.

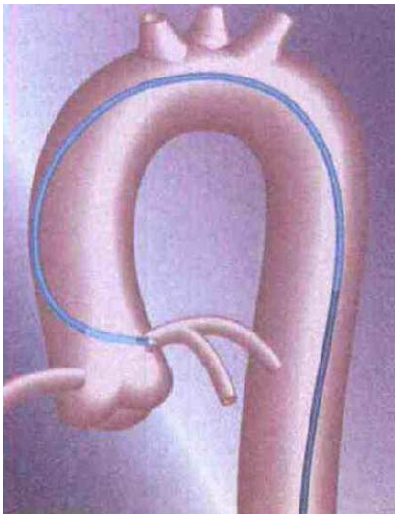
[54] Trial Transcript, at 627:19-22.

[55] Trial Transcript, at 621:12 – 623:19.

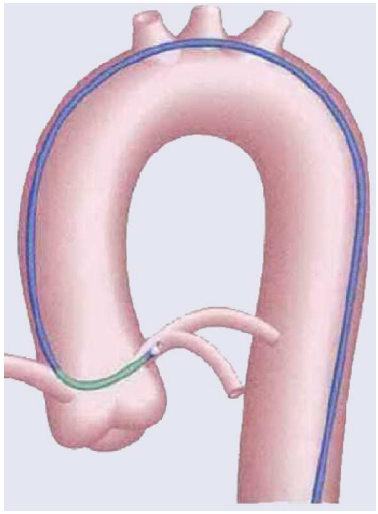
[56] Trial Transcript, at 622:6-7.

undetermined length of engagement so that even Dr. Voda was unable to determine if it was more or less than 1.5 cm.

Further, Dr. Voda's inducement argument is undercut by comparing the illustrations of Medtronic catheters he alleges infringe (EBU) to other Medtronic catheters he admits do not infringe. Shown below are illustrations of the EBU and Medtronic's Champ curve.[57]



EBU (accused)



Champ (noninfringing)

Dr. Voda admitted that Medtronic's Champ catheter does not infringe,[58] but the illustrations for the Champ show far more contact on the opposite wall than the EBU.[59] Dr. Voda further testified that the Kiesz curve (sold by Boston Scientific) is not covered by his license and thus would not infringe, even though the marketing materials show far more contact for the Kiesz curve than for the EBU.[60]

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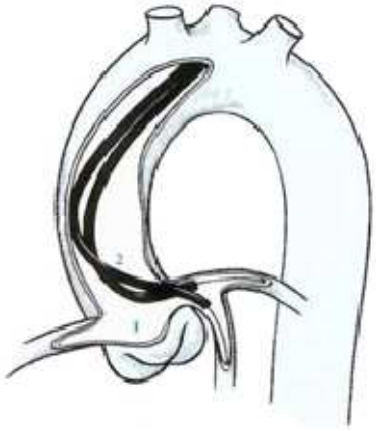
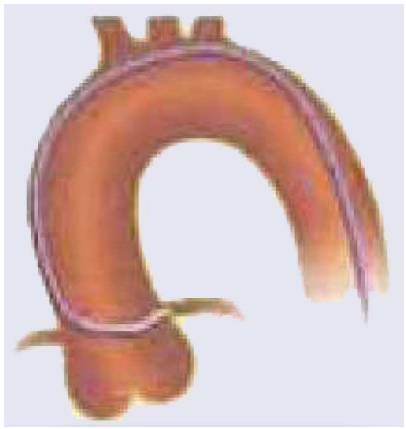
[58] Trial Transcript, 625:12-5, 627:8-10; Plaintiff's Trial Exhibit 183.

[59] Trial Transcript, 626:16-23.

[60] Trial Transcript, 630:5 – 631:23.



EBU (accused)[61]



Kiesz (noninfringing)[62]

Dr. Voda has not shown a single written or verbal instruction from Medtronic directing doctors to use the EBU to contact the opposite aortic wall for 1.5 cm or more. Accordingly, there is no evidence of any active inducement of infringement and no evidence that any physician was actually induced.

4. Dr. Voda adduced no evidence of specific intent to induce infringement.

Even if Plaintiff had shown *acts* that induced physicians to practice the claimed method—and he did not—his inducement claim would still fail because Plaintiff did not show that Defendants knew or were willfully blind to the alleged direct infringement by physicians. *Global-Tech*, 131 S. Ct. at 2068.

Of course, the fact that Medtronic's catheters are capable of non-infringing uses—as Plaintiff admitted—makes it impossible for Medtronic to have specifically intended

[61] Defendants' Exhibit 69.

[62] Plaintiff's Exhibit 322, at 1593. Mr. Schmiel testified the Kiesz curve has more engagement along the contralateral aortic wall than the VODA and CLS curves. *See* Trial Transcript, at 1095:12-13 (playing of video recording of deposition of Daniel Schmiel, at 72:24 – 74:14) (Dec. 21, 2011) (Exhibit 2).

for any physician use the catheter in an infringing way. *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc) ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities."). It is undisputed Medtronic advertised and promoted its EBU catheters for use in noninfringing ways.[63]

On top of this evidence, Medtronic has its own patent (the Brin patent) which covers the EBU catheter. The Brin patent was filed and issued before the '213 patent.[64] The evidence is undisputed that Medtronic, and in particular its sales representatives, believed that the EBU was proprietary technology because of the Brin patent.

> Q. Can you tell us what that says?
> A. It says number one seller at Medtronic, patented curve, curve exclusive to Medtronic.
> Q. Why did you make a note there "patented curve"?
> A. Because that's what we were told and I thought, hey, you know, you're always looking for an angle or an edge in sales. So, you know, at the time I thought, hey, we're the only ones that have this. This is great, you know, gives me and advantage against the competition.
> Q. So the whole time you sold the EBU you have always believed that Medtronic had a patent on it?
> A. Yes.[65]

Medtronic's sales representatives never subjectively believed the EBU infringed because of the Brin patent. There was no evidence that this belief was dishonestly held or was the result of willful blindness.

Because no reasonable fact finder could have found that Medtronic specifically intended to induce infringement, JMOL is warranted. At the very least, the verdict of

[63] *See* Defendants' Trial Exhibit 6, Plaintiff's Trial Exhibit 247.

[64] *See* Defendants' Trial Exhibit 246 (Brin Patent).

[65] Trial Transcript, at 983:15 – 984:1; *See* Plaintiff's Trial Exhibit 14, at 13.

induced infringement is against the great weight of the evidence, and Medtronic is entitled to a new trial on this issue.

C. Plaintiff Failed to Carry His Burden of Proving Contributory Infringement, and the Great Weight of the Evidence Is to the Contrary.

The Patent Statute established liability for contributory infringement as follows:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (emphasis added). Plaintiff bears the burden of proving by a preponderance of the evidence that the EBU catheter is not "suitable for substantial non-infringing use." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 489 (1964); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004). Proof of contributory infringement also requires the same specific intent as an inducement claim: knowledge, or willful blindness to the fact, that "the combination for which his component was especially designed was both patented and infringing." *Aro*, 377 U.S. at 488; *see also Global-Tech*, 131 S. Ct. at 2067.

It is well-settled that a noninfringing use is "substantial" when it is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). The question is not whether, and to what extent, an apparatus has in fact been put to a non-infringing use, but

whether it is suitable for such use. *E.g.*, *Applera Corp. v. MJ Research, Inc.*, No. 3:98cv1201, 2004 U.S. Dist. LEXIS 2929, at *13 (D. Conn. Feb. 24, 2004) (citing *Aro*, 377 U.S. at 479, 487-88 & n. 7) ("Questions of substantial non-infringing use in the '675 and '610 context therefore will not focus on whether the component enabled PCR or cycle sequencing but focus on whether or not the component is suitable for use in thermal cycler models or systems which do not infringe the '675 and '610 Patents.").

In the present case, the record evidence is both overwhelming and unrefuted that (a) the EBU is a commodity product, (b) the radial approach is a non-infringing use, (c) the EBU is suitable for the radial approach, and (d) the radial approach is a substantial use under Federal Circuit case law.

First, Mr. Acebo, Medtronic's sales representative, testified (without contradiction) that stents, balloons, and guide catheters, including the EBU, are commodity products.[66] Second, Dr. Voda repeatedly admitted that the radial approach is a non-infringing use.[67] Third, Dr. Voda testified that the EBU "certainly can be used for" the radial approach.[68] Mr. Horrigan testified not only that the EBU can be used for a radial approach, but that he has personally observed doctors use the EBU for radial procedures.[69] Similarly, Dr. Uretsky testified that he has personally used the EBU catheter to perform the radial

[66] Trial Transcript, at 963:4-13.

[67] Trial Transcript, at 613:10-12, 613:24-614:13, 615:1-7.

[68] Trial Transcript, at 526:15-19.

[69] Trial Transcript, at 1064:16-1065:6.

approach.[70] Mr. Schmiel of Boston Scientific testified that the EBU is one of the most popular catheters for the radial approach.[71] Dr. Voda disputed none of this testimony.

Plaintiff argued that the radial approach is not a substantial use ostensibly because the radial approach is used in a low percentage of angioplasties in the U.S. However, Dr. Voda admitted the exact opposite on direct examination—that the use of the EBU for a radial approach is both substantial and noninfringing:

> Q. Dr. Voda, with respect to the EBU catheters, are you aware of any uses of the EBU catheters that would be substantial in the marketplace, and yet, at the same time, would not practice the method of claim one?
>
> A. Yes. The catheter that apparently is used for radial approach, apparently EBU is also manufactured for that approach, so this would be catheters that would not infringe on Voda catheter.[72]

This party admission alone should be dispositive of the substantial use issue. Dr. Chronos tried to characterize the use of the radial approach in the United States as "minimal,"[73] but later admitted that the radial approach is used in "five percent, ten percent" of angioplasties.[74] He also testified that at his hospital one of his practice partners is "doing lots of cases" using the radial approach, and that his hospital made a special effort to expand its facilities to accommodate radial procedures.[75] Dr. Chronos

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[70] *See* Trial Transcript, at 1128:22-24.

[71] *See* Trial Transcript, at 1095:12-13 (playing of video recording of deposition of Daniel Schmiel, at 132:11-21) (Dec. 21, 2011) (Exhibit 2).

[72] *See* Trial Transcript, at 524:23-525:5 (emphasis added).

[73] *See* Trial Transcript, at 721:25-722:6.

[74] *See* Trial Transcript, at 750:25-751:4.

[75] Trial Transcript, at 748:15 – 750:3.

also testified that the radial approach has certain advantages over the femoral approach,[76] and that there are some situations in which the radial approach is the only approach that can be used to perform angioplasty.[77] Indeed, Dr. Chronos specifically testified that the radial approach is an "accepted respected way to do an angioplasty."[78] And this testimony is all from Plaintiff's witnesses. Dr. Uretsky testified that the radial approach is used for "somewhere between five to ten percent" of angioplasties in the United States, and he confirmed that the radial approach is not unusual or experimental, but rather is an acceptable method of performing an angioplasty.

Mr. Schmiel (Boston Scientific) testified similarly, and his testimony was confirmed by a medical journal article containing survey data of U.S. radial procedures showing the popularity of the EBU for such procedures."[79] The article confirmed that the EBU was the "most popular" catheter for use in radial procedures targeting left anterior descending (LAD) and circumflex (Cx).[80] All of this testimony is undisputed.[81]

The overwhelming weight of the evidence in this case—indeed all of the evidence—leads to the conclusion that the EBU is a commodity product that is capable of substantial noninfringing use. Moreover, the absence of evidence that Medtronic knew (or was willfully blind to the fact) that any doctors directly infringed (see *supra* pg. 17-

[76] *See* Trial Transcript, at 751:5-7.

[77] *See* Trial Transcript, at 753:8-18.

[78] *See* Trial Transcript, at 754:8-10.

[79] *See* Trial Transcript, at 1095:12-13 (playing of video recording of deposition of Daniel Schmiel, at 132:11-21) (Dec. 21, 2011) (Exhibit 2); Plaintiff's Exhibit 322, at 1606.

[80] Plaintiff's Trial Exhibit 322, at 1611.

[81] *See* Trial Transcript, at 1127:20-1128:24.

18) defeats Dr. Voda's argument that Medtronic specifically intended to contribute to such infringement. There was insufficient evidence for a reasonable jury to find otherwise, and therefore JMOL should be granted in favor of Medtronic on the issue of contributory infringement.

D. Plaintiff Failed to Carry His Burden of Proving Willful Infringement, and the Great Weight of the Evidence Is to the Contrary.

To establish willful infringement, Dr. Voda was required to show by clear and convincing evidence that Medtronic "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent" and "the objectively defined risk ... was either known or so obvious that it should have been known to the accused infringer." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007).

For the objective prong, Dr. Voda failed to prove that Medtronic's defenses were so insufficient such that Medtronic was acting with an unjustifiably high risk that it was infringing the claims. Medtronic, as shown above, has very strong noninfringement positions. Medtronic also justifiably relied on the reexaminations of the patents, where the PTO initially rejected the patents twice as invalid due to the prior art and found substantial new questions of patentability.[82]

The Federal Circuit has ruled that *Seagate's* objective standard cannot be met where the infringer offers legitimate defenses to infringement and credible invalidity arguments. *See Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 260 F.App'x 284, 291

[82] *See* Final Pretrial Report, ¶¶ 8, 10 (Dkt. No. 193). Dr. Voda initially entered the reexaminations as evidence, but the Court later removed them from the record based on Dr. Voda's request. Medtronic asserts this is error. *See* Medtronic's Motion for New Trial, Section III. E, fn 49.

(Fed. Cir. 2008). In *Black & Decker*, the plaintiff asserted infringement of two patents related to a combination rugged jobsite radio/battery charger. The jury found willful infringement, and the trial court granted JMOL for the plaintiff on the defendant's invalidity defenses. On appeal, the Federal Circuit vacated the willfulness verdict and stated that a willfulness finding was unlikely to be supported where the district court had observed that the defendant had "legitimate defenses" to the plaintiff's infringement claims and offered credible invalidity arguments. *Id*. at 291 (internal citations omitted). As in the *Black & Decker* case, Medtronic certainly has legitimate, and indeed strong non-infringement arguments, including Dr. Voda's admissions that both radial and femoral uses of the EBU do not infringe. In addition, the PTO has twice agreed that the relevant claims of the patent-in-suit may be invalid. Accordingly, the evidence does not suggest an objectively high likelihood that Medtronic's EBU catheter infringed any valid claims of Dr. Voda's patent.

For the subjective prong, Dr. Voda failed to show any intent by Medtronic to infringe his patents. Mr. Horrigan testified Medtronic did not copy, and had no intent to copy, the VODA catheter.

> Q. The Design 1 is stick with the EBU like you designed it --
> A. Correct.
> Q. -- as opposed to changing it to be like Voda?
> A. Correct.
> Q. Look at the reasons why that made sense, one?
> A. It matches the curve design that we have filed the patent upon.[83]
>
> * * *
>
> Q. So let's now go talk about one, why did number one matter to you?

[83] Trial Transcript, at 236:3-9.

> A. Well, we knew of the existence of the XB, and we knew that, you know, Cordis really had no business copying somebody else's patented curve and selling it. We knew other people were doing it, too, and we knew they had no business doing it. We designed and patented our own curve, we went through all of this trouble of getting the sizing correct, to Judkins, and it seemed almost ludicrous to me that because one physician, who clearly was an important physician, and did a lot of business with us, said that we should cut bait and change back and copy somebody else's curve, seemed absolutely ludicrous.[84]

In fact, Medtronic provided memos showing Medtronic specifically chose not to copy the VODA design, even though some doctors requested it.[85] Dr. Voda failed to provide any evidence to rebut this testimony.

Further, Dr. Voda did not dispute Mr. Horrigan's explanation of the independent development of the EBU catheter technology. Medtronic obtained its own patent, the Brin patent, on the EBU catheter.[86] The Voda patents were cited on the face of the Brin patent. This is evidence Medtronic reasonably believed that the PTO looked at Dr. Voda's patents and concluded that the EBU was different.

The Federal Circuit has observed that a defendant's reliance on the issuance of its own patent is evidence that a defendant reasonably believed his actions were protected within its own patently distinct claims and outside the claims of plaintiff's patent. *See King Instruments Corp. v. Otari Corp.,* 767 F.2d 853, 866-67 (Fed. Cir. 1985). In *King*, the patents-in-suit related to automated machines for loading magnetic audio or video tape into closed cassettes. The court had found the plaintiff's patent was infringed but

[84] Trial Transcript, at 237:1-12.

[85] *See* Trial Transcript, at 234:5 – 236:2; 243:14 – 244:8-17.

[86] Defendants' Trial Exhibit 246.

determined that the plaintiff was not entitled to increased damages or attorneys' fees. The patentee appealed arguing that enhanced damages should have been awarded based on evidence that suggested willfulness, including the defendant having obtained an early version of plaintiff's machine and then later filing its own patent application. The Federal Circuit rejected this argument, observing that the evidence was consistent with a scenario where the defendant was attempting to design around the claims of the plaintiff's patent, and reasonably believed that his actions were protected as within the scope of his own patent while falling outside the plaintiff's. *Id*. at 866-67.

Similarly, in *Presidio Components Inc. v. American Technical Ceramics Corp.*, 723 F. Supp. 2d 1284, 1323 (S.D. Cal. 2010), the court held that the plaintiff Presidio failed to show by clear and convincing evidence that the defendant ATC acted with the necessary subjective intent where the PTO considered and allowed a patent submitted by ATC, even after initially rejecting the application in light of the plaintiff's patent. *Id*. at 1323. Accordingly, a finding by the jury of willful infringement was not supported by substantial evidence.

Medtronic reasonably believed that its actions were protected within its own patentably distinct claims in the Brin patent. JMOL is required because no reasonable fact finder could have concluded, on this record, that Medtronic was "objectively reckless" in designing the EBU catheter or that it had the necessary subjective intent to infringe willfully. The great weight of the evidence is contrary, warranting a new trial.

E. Plaintiff Failed to Carry His Burden of Proving Damages, and the Great Weight of the Evidence Supports a Different Royalty Calculation.

By statute, the damages for infringement are set at an amount "adequate to compensate for the infringement." *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1383 (Fed. Cir. 2004). The jury's calculated royalty rate of 14.2% is against the great weight of the evidence as it is higher than even Dr. Voda's expert testified was appropriate.

Dr. Voda's damages expert, Dr. Wu, suggested a proposed royalty rate of 11%. Even this figure is fatally flawed, as Dr. Wu failed to provide a reasonable basis for the number, which is significantly higher than any previous royalty rates for the '213 patent. Dr. Wu began his analysis by improperly taking the 7% royalty from the Scimed Agreement as his baseline. That agreement cannot justify a 7% baseline royalty, however, because it included far more than just a license to the relevant patent—the Scimed Agreement also

a. granted a worldwide scope.[87]
b. provided exclusive rights.[88]
c. provided exclusive use of the Voda trademark.[89]
d. included rights to any pending patent applications, and specifically included all foreign patents, including exclusive rights to at least three patents besides the '213 patent—U.S. Patent Nos. 6,501,258; 6,445,625; and 6,475,195.[90]
e. consulting services provided by Dr. Voda.[91]

[87] Trial Transcript, at 901:11-14.

[88] Trial Transcript, at 900:25-901:3.

[89] Trial Transcript, at 901:8-10.

[90] *See* Trial Transcript, at 903:1-10.

[91] Trial Transcript, at 908:5-7.

f. included the right to sue others for patent infringement and keep some of that money.[92]
g. included the right to sublicense to others to practice the patent.[93]

These characteristics rendered the Scimed 7% royalty unreliable as the baseline. *See, e.g., ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) (rejecting reliance on licenses that "conveyed rights more broad in scope than those covered by [plaintiff's] patent"). Remarkably, Dr. Wu's testimony was that these additional provisions did not matter for purposes of his analysis, and thus did not factor into his analysis.[94] This is not a justification; it is an admission of error. *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1328 (Fed. Cir. 2008) (vacating royalty award where the patentee's expert "supplied no explanation to the jury about the subject matter or patents covered by [the license] agreements"); *Trell v. Marlee Electronics Corp.*, 912 F.2d 1443, 1447 (Fed. Cir. 1990) (vacating royalty award due to "apparent failure to consider the fact that the … license was exclusive").

Similarly, Dr. Wu failed to consider or simply ignored key differences between the hypothetical negotiation and the Cordis settlement. The Cordis settlement involved a grant of worldwide rights and included three different patents.[95] Dr. Wu admitted he

[92] Trial Transcript at 908:5-19.

[93] *See* Trial Transcript, at 909:17-20.

[94] Trial Transcript, at 934:25-935:23 (emphasis added).

[95] Trial Transcript, at 920:9-14.

failed to allocate the value of the three patents involved in the Cordis settlement relative to one another.[96]

The Federal Circuit has explained that in considering prior license agreements as part of the *Georgia Pacific* analysis, it is important to isolate the value properly attributable to the patent at issue. *See Uniloc U.S.A., Inc. v. Microsoft Corp*., 632 F.3d 1292, 1316-18 (Fed. Cir. 2011) (district court must consider licenses that are commensurate with what the defendant has appropriated; court should not rely on unrelated licenses to increase the reasonable royalty rate above rates more clearly linked to the economic demand for the claimed technology); *ResQNet.com,* 594 F.3d at 869 ("Any evidence unrelated to the claimed invention does not support compensation for infringement but punishes beyond the reach of the statute.").

Dr. Wu also erred by ignoring evidence that suggested Medtronic would have negotiated a capped royalty. Medtronic signed such an agreement in the only arm's length, negotiated license agreement for backup catheter technology considered by Dr. Wu involving Medtronic. In that agreement, Medtronic capped the overall maximum royalty payment to the patent holder at $750,000.[97] This arrangement was similar to Dr. Voda's settlement with Abbott, which paid $1.1 million for a royalty-free license in perpetuity. [98]

[96] Trial Transcript, at 923:8-10.

[97] *See* Trial Transcript, at 927:12-928:5.

[98] *See* Trial Transcript, at 915:13-22.

In light of these problems with the 11% royalty figure Dr. Wu calculated as a reasonable royalty, the jury's decision to go beyond this number to a royalty rate of 14.2% is simply unsupportable; it is at the very least against the great weight of the evidence. Instead, the proper calculation was Dr. Becker's assessment, which considered the impact of the differences between these assignments and determined that the reasonable royalty should be 2%.

Dr. Wu additionally failed to provide any royalty base in his expert report or in his testimony. Instead, he simply stated that all Medtronic EBU sales would be the appropriate base without tying that royalty base to any alleged infringing conduct. There must be some foundation for a royalty base asserted. *See Lucent Technologies Inc. v. Gateway, Inc.*, 509 F. Supp. 2d 912, 937 (S.D. Cal. 2007) ("[S]imply because Dell and Gateway sell computers does not automatically designate the computer as the royalty base"; where there was insufficient evidence to establish proper royalty base from the evidence at trial, jury verdict overturned and court grants new trial) *aff'd*, 543 F.3d 710 (Fed. Cir. 2008). The jury's decision to apply the royalty rate to all catheters, where the record was clear that not all EBU catheters infringe, was error. Accordingly, Medtronic respectfully requests a new trial on that basis, or in the alternative, that the Court grant a remitter to reduce the damages award to the 2% reasonable royalty proffered by Dr. Becker.

IV. CONCLUSION

For the foregoing reasons, Medtronic respectfully request that the Court grant its motion for JMOL or in the alternative a new trial.

Date: February 24, 2012

Respectfully submitted,

/s/ Michael Simons

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CERTIFICATE OF SERVICE

I certify that on February 24, 2012, a true and correct copy of the foregoing electronically filed document was served on the parties listed below via first class mail, postage prepaid, unless said party is a registered CM/ECF participant who has consented to electronic notice, and the Notice of Electronic Filing indicates that Notice was electronically mailed to said party:

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